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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/766,378 | 01/19/2001 | Peter R. Rhode | 48002-DIV (1758) | 8910 |

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EXAMINER

DECLOUX, AMY M

ART UNIT PAPER NUMBER

1644

DATE MAILED: 07/15/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|---------------|--------------|
| Office Action Summary | Applicant No. | Applicant(s) |
| | 09/766,378 | RHODE ET AL. |
| Examiner | Art Unit | |
| Amy M. DeCloux | 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 06 May 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) 1-24 and 31-37 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 25-29 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 19 January 2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

4) Interview Summary (PTO-413) Paper No(s) _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group XVIII, claims 25-29, and the species illustrated in Figure 9B, in Paper No. 5, filed 5-6-02, is acknowledged. Since no prior art on the elected species was found the search has been moved to a complex of the recited formula ABC. The traversal is on the ground(s) that the search and examination for many of the groups specified in the restriction of the present application would be substantially coextensive particularly in view of the search and examination that has already been conducted for parent case US Patent 6, 232,445. This is not found persuasive because with regard to the parent case, because each case is prosecuted on its own merits, and it is further noted that the examiners on the instant case and said parent case are not identical. Since applicant did not specifically contest the reasons for the restriction outlined in the restriction requirement mailed 3-16-02, the restriction is maintained for essentially the reasons of record.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-24 and 30-37 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5, filed 5-6-02.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Oath/Declaration

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Specifically see non-initialed and non-dated alterations to the name of the second inventor, and to several attorneys names.

Specification

5. The abstract of the disclosure is objected to because of the use of the term "novel" in line 1 of the abstract. Correction is required. See MPEP § 608.01(b).

6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

7. Claims 25 and 28 are objected to because of the following informalities: the semicolon at the end of the phrase of part C should be replaced by a comma, to be consistent with the punctuation at the ends of part A and part B. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 25 and 27-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 25 and 27-28 are indefinite in the recitation of "molecule the same" which is recited in lines 8 and 10 of claim 25, and lines 10 and 12 of claim 28, because it is not clear what is meant. Inserting the phrase "which is" after the word "molecule" is one way to overcome the rejection.

B) Claim 25 and dependent claim 27 is indefinite in the recitation "complex comprising an sc-MHC class following general formula" because it is not clear what is meant.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in–
 - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b)

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only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

11. Claims 25-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Hirsh et al. (US Patent No. 6,211,342, Issued 4-3-02, filed 7-18-1996).

‘342 teaches a multivalent MHC complex comprising a plurality of MHC molecules including MHC Class II molecules, in which the alpha and the beta chains can be connected by a tether (see column 2, lines 44-48, lines 55-65 and column 4, lines 21-28), a linker connecting the MHC molecules, and said linkers can include immunoglobulin chains or fragments thereof, can be a cognate moiety for a cell surface antigen, a zinc finger motif and a leucine zipper (see column 2, lines 45-48, column 3, lines 15-50), a peptide loaded into the MHC molecules, wherein said peptide can be loaded into the molecule, or covalently attached by crosslinking, or a peptide sequence can be incorporated into the DNA sequence encoding the fusion protein (see entire patent, especially column 2, lines 43-51 and column 3, lines 50-60). ‘342 also teaches that said complex can be tagged with toxins such as ricin and diphtheria toxin (see entire patent, especially column 4, lines 1-9. Therefore, the referenced teachings anticipate the claimed invention.

12. Claims 25-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Rhode et al. (US Patent No. 5,869,270, Issued 2-2-99, filed 1-31-1996). It is noted that the referenced inventive entity is not identical to the instant inventive entity, and hence is “other”.

‘270 teaches polyspecific MHC complex fusion molecules comprising MHC single chain molecules, joining molecules such as immunoglobulin or chemically crosslinked to dendrimers which can link cysteines present in the c terminus of the beta chain of an MHC molecule, and effector molecules such as B7 or B7-2 or a radioactive tag or other detectable tag such as biotin, I12 or other protein tag (see entire patent including column 15, lines 4-9, 62-67, column 16, lines 1-25, 36-42, column 19, lines 45-67). ‘270 also teaches that said empty single chain class II molecules can be made and that the peptides can be loaded onto the empty molecule (see column 16, lines 61-67, column 17, lines 34-38 . Therefore, the referenced teachings anticipate the claimed invention.

13. No claim is allowed. However, it is noted that the elected species was found free of the prior art.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, PhD,
Patent Examiner, Group 1640,
July 15, 2002

Amy DeCloux
7-15-02